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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,094	12/31/2003	Gautam Vinod Daftary	B2351010.1	6940
26158 7590 10/26/2007 WOMBLE CARLYLE SANDRIDGE & RICE, PLLC ATTN: PATENT DOCKETING 32ND FLOOR P.O. BOX 7037 ATLANTA, GA 30357-0037			EXAMINER KISHORE, GOLLAMUDI S	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 10/26/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/748,094

Applicant(s)

DAFTARY ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-22, 61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-22 and 61-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The amendment dated 10-23-07 is acknowledged.

Claims included in the prosecution are 1-8, 10-22 and 61-62.

In view the amendment, the 112, 2<sup>nd</sup> paragraph rejection is withdrawn.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-8, 10-22 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirpotin (6,110,491).

Kirpotin discloses a method of preparation of liposomes by forming a lipid film and hydrating it with a buffer containing ammonium sulfate (Example 7). Kirpotin also teaches that if necessary, to achieve an osmolarity of 377 mmol/kg, sucrose could be added to the medium (Example 8). The liposomes contain hydrogenated egg phospholipid and cholesterol. Doxorubicin is loaded into the preformed liposomes (Example 7). What is lacking in Kirpotin is the teaching of the amount of aqueous medium added to per mol phospholipid. However, since the final product in Kirpotin is a liposome just as in instant case, in the absence of showing unexpected results, it is

deemed obvious to one of ordinary skill in the art to vary the amounts of the hydrating medium to obtain the best possible results.

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that Kirpotin does not teach or suggest a process for the manufacture of long circulating non-PEGylated liposomes as set forth in claim 1. This argument is not persuasive since Kirpotin teaches the method of preparation of non-PEGylated liposomes. Applicant further argues based on the declaration by MR. Annappa that instant invention provides unexpected results compared to the PEGylated liposomal preparation (CAELYX) marketed currently. These arguments are not persuasive since the proper comparison to show unexpected results would be the comparison with Kirpotin and not with the commercially available PEGylated product since this product was not used in the rejection. Instant claims recite a process of preparation of liposomes containing phospholipids and sterol, which are not PEGylated and Kirpotin, teaches the preparation of non-PEGylated liposomes.

3. Claims 1-8, 10-22 and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forssen (5,714,163) in combination with Janoff (4,880,635).

Forssen discloses a method of preparation of liposomes wherein the lipid film is hydrated with ammonium sulfate. The liposomes contain DSPC and cholesterol and vincristine. Vincristine is added to the preformed liposomes (Example 1). Although Forssen teaches the use of 300 mM sucrose, he does not teach the use of hydration buffer containing both ammonium sulfate and sucrose.

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Janoff teaches that sugars such as sucrose when present both inside and outside would enable the liposomes to retain Adriamycin during dehydration and rehydration (col. 21, line 23 through col. 21, line 27).

To include sucrose in the hydration medium of Forssen would have been obvious to one of ordinary skill in the art since such a procedure would enable the presence of sucrose within the liposomes as well as outside and since Janoff teaches that the liposomes retain the active agent during dehydration and rehydration procedures. Although Forssen does not specifically teach the amount of aqueous medium added per mol phospholipids, since the final product in Forssen is a liposome just as in instant case, in the absence of showing unexpected results, it is deemed obvious to one of ordinary skill in the art to vary the amounts of the hydrating medium to obtain the best possible results.

Applicant's arguments have been fully considered, but are not persuasive. Applicant's arguments once again are based on the declaration by Mr. Annappa to show unexpected results. As pointed out above, since the rejection is based on the Forssen and Janoff and not based on the commercially available product CAELYX, the proper comparison would be with the applied prior art teachings. The rejection therefore, is maintained.

**4. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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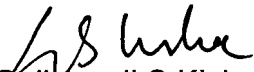
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK